

A NEW PROCESS FOR THE ACCELERATION TEST AND EVALUATION OF AEROMEDICAL EQUIPMENT FOR U.S. AIR FORCE SAFE-TO-FLY CERTIFICATION

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Aeromedical flight equipment must meet airworthiness criteria according to Department of Defense Handbook MIL-HDBK-516, *Airworthiness Certification Criteria*, MIL-STD-810G, and MIL-STD-1791, which requires restraint of any item that may potentially cause injury to personnel during emergency landings, an over-water ditching, or crash loads. Several government standards provide adequate descriptions of *acceleration test* methods; however, none formally documents a non-destructive test method to qualify equipment as safe-to-fly (STF). Using the USAF fixed-wing aircraft STF test criteria, this article presents a structured process developed by the Aeromedical Test Branch, 77th Aeronautical Systems Group, to assess equipment as STF. Further, it demonstrates the application of this process to meet the acceleration requirements for *aeromedical evacuation* equipment.

Keywords: *Acceleration Test, Aeromedical Equipment, Safe-to-Fly Process, Test and Evaluation, Aeromedical Evacuation, USAF Aircraft*

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Generally speaking, medical devices are designed to function in environmentally controlled locations, such as stationary hospitals, and not within the harsh, dynamic aircraft environment. Yet, the same medical devices used to care for patients in a hospital environment are often the most capable devices for patient care during transport from one facility to another. These missions are called aeromedical evacuations (AE) missions, and they provide life-sustaining care for a vast array of patients. However, because the devices are designed for a controlled environment, concerns they may adversely affect the operation of aircraft systems must be addressed. Conversely, the aircraft may adversely affect the proper operation and efficacy of the medical equipment.

USAF STF Test Process for AE Equipment

Failure of medical devices during in-flight medical care may result in exposing patients and aircrew to hazardous situations. All medical equipment identified for use on U.S. Air Force AE fixed-wing aircraft must undergo a STF test process in accordance with Section 2.5.1.7 of Air Force Instruction 11-202 (Department of Air Force, 2006), before the STF certification can be issued by the authorizing aircraft system organizations. Military standards, civilian regulations, and professional experience and expertise are all part of the STF evaluation package.

A typical STF evaluation features three phases.

Phase I: Baseline Assessment

The purpose of the baseline assessment is to verify that the equipment under test (EUT) operates in accordance with the manufacturer's specifications and the operator's manual. The EUT is evaluated for adherence to optimum human factors referenced in MIL-STD-1472F (Department of Defense, 1999) and basic electrical safety requirements. The test team becomes familiar with the equipment to select the appropriate tests based on the U.S. Air Force AE equipment test requirements. From there, the team identifies the tie-down configuration, aircraft interfaces, and operational use of the equipment during the baseline assessment. The test plan is then developed and submitted to the aircraft system organizations for review prior to starting the laboratory tests.

Phase II: Laboratory Tests

The purpose of the laboratory testing phase is to simulate the operational in-flight environment through testing, which is modeled after a series of worst-case event scenarios, such as a rapid decom-

pression event or other aircraft incidences or mishaps. Military and industrial standards are used as guidance to select the tests and establish the test criteria. Typical laboratory tests include vibrations, electromagnetic interference (EMI), hot and cold temperature extremes for operational use and storage, humidity, explosive atmosphere, altitude, rapid decompression, and acceleration.

Prior to 2006, specific types of aircraft were dedicated almost exclusively to AE missions. The use of medical devices during flight was a routine part of the daily mission, and acceleration testing was not a solid STF test requirement. Since then, refinements in the employment of cargo aircraft have enabled a broader array of assets for AE and other transport missions. This change allows any available cargo aircraft, or "opportune aircraft," to be quickly designated and configured as an AE transport aircraft. While this fundamental shift in operations greatly benefited the overall AE mission, more exhaustive testing procedures were implemented to assess medical devices prior to in-flight use to ensure safety across the numerous aircraft fleets. These devices were now expected to conform to typical airlift standards just as any other cargo brought on board. The most notable change to the testing procedures was the addition of more robust acceleration testing requirements. After the AE test article completes the laboratory phase, an In-Flight Assessment (IFA) may begin.

Phase III: IFA

The purpose of conducting an IFA for AE equipment is to perform functional checks on board the aircraft during an aeromedical readiness mission. The controls, visual and audible alarms, and display screen of the AE equipment are observed and evaluated during the flight. Test personnel interact with and solicit feedback from AE crewmembers regarding the device's form, fit, and function. These data are used to identify any remaining issue with the use of the device that may not arise during the simulated laboratory test scenarios. Further, this final phase also assists in evaluating and solidifying the intended concept of operations for the device.

Acceleration Testing

AE equipment must meet airworthiness criteria according to MIL-HDBK-516B (Department of Defense, 2008). The criteria require items that could cause injury to personnel during emergency landings, ditching, and crash loads to be restrained. Since aeromedical devices are not mission-critical equipment and are typically considered carry-on equipment, the main thrust for acceleration testing hinges on the

inertial loads where safety is paramount. Successful completion of acceleration testing ensures AE equipment can sustain acceleration loads found in aviation mishaps and, more importantly, ensures the safety of the aircraft's occupants. Ultimately, testing is used to ensure medical devices or any cargo does not adversely impact any chance of survival or impede or prohibit passengers' egress. Additionally, high levels of acceleration may have detrimental effects on the AE equipment, leading to broken fasteners, supports, and mounting components. Failures such as these may result in insufficient restraint of the device or its components, ultimately allowing it to become a projectile during a typical crash scenario. Therefore, the equipment's mounting and/or restraint methods must be tested to verify that they will not fail and subelements can be properly contained within the system during an acceleration event.

Acceleration, as addressed in MIL-STD-810G Method 513.6 (Department of Defense, 2009), is a load factor (inertial load or "g" load) that is applied slowly enough and held steady for a period of time such that the materiel has sufficient time to fully distribute the resulting internal loads to all critical joints and components. The common methods used to expose equipment to a sustained acceleration load are centrifuge and track/rocket-powered-sled testing. However, both methods impose limitations on AE equipment testing. For example, the costs required and the scheduling, planning, and coordination phases associated with the use of these types of test facilities are often prohibitive. In some cases, centrifuges and track/rocket sleds may limit the orientations at which the test article can be mounted for testing. To maintain validity, all AE devices are tested under the same mounting configuration as intended for operational use. Finally, due to the often expensive and delicate nature of medical devices, insufficient inventories often prevent the use of these tests due to their somewhat destructive nature.

Because of the difficulties associated with physical dynamic testing, the ATB team initially turned to Finite Element Analysis (FEA) as the method of choice for meeting acceleration test requirements. Recent technological advances in microcomputing and higher resolution graphics capabilities allowed complex systems to be modeled and simulated for both static and dynamic tests.

The FEA techniques were already used by others for various aircraft structures and devices. For example, Foster and Sarwade (2005) performed an FEA of a structure that attached medical devices to a litter. This structure was later approved as STF. Continuing on the same theme, Lawrence, Fasanella, Tabiei, Brinkley, and Shemwell (2008) studied a crash test dummy model for NASA's Orion crew module landings using FEA. Viisoreanu, Rutman, and Cassatt

(1999) reported their findings for the analysis of the aircraft cargo net barrier using FEA. Furthermore, Motevalli and Nouredine (1998) used an FEA model of a fuselage section to simulate the aircraft cabin environment in air turbulence. These and similar studies demonstrated the successful use of the FEA method to verify requirements by analysis for an acceleration test.

Given the costs associated with dynamic testing, the ATB originally envisioned using the FEA method to alleviate budget and inventory concerns. To test this theory, the ATB employed FEA for testing various AE structures to meet the acceleration requirements and found some aspects of this method to be cost- and time-prohibitive. Lessons learned from these studies are provided in the case-studies section.

The various types of analysis and test methods raise questions as to what the correct decision process is for selecting the most appropriate method for STF testing of AE equipment. The authors of this article describe the process developed and employed by the ATB for the acceleration testing of AE equipment since June 2008. The ATB's process has proven to be well suited for identifying the most appropriate test method—one that not only represents the most appropriate and effective test method, but also minimizes the use of available resources. This process includes testing both structurally simple and complex equipment and successfully introducing the use of the Equivalent Load Testing (ELT) method, which permits the use of alternative testing approaches, such as pull testing and tensile testing.

ATB's Acceleration Test and Evaluation Process

Process Description

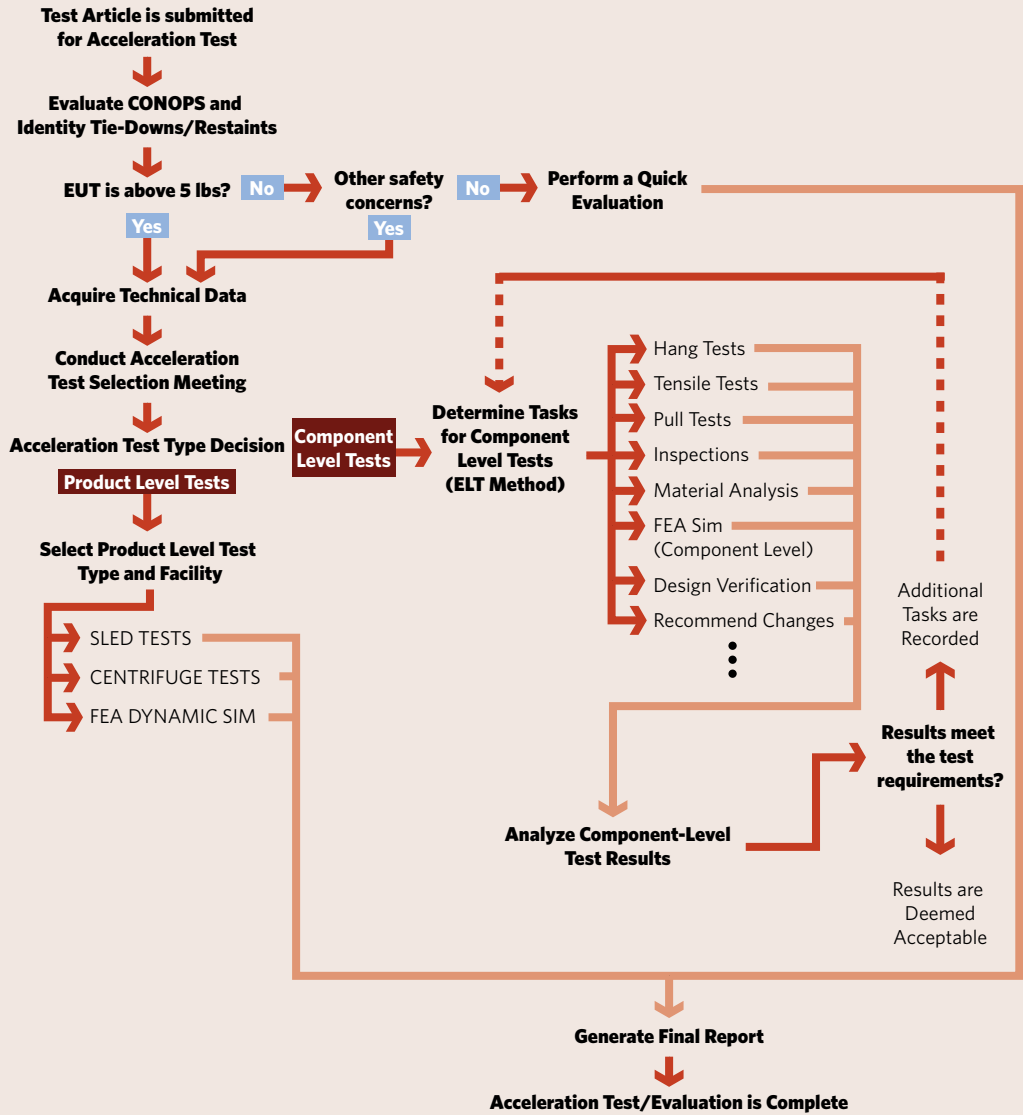
An integrated team approach remains the cornerstone for the acceleration *test and evaluation* process for AE STF certifications. The team members, each having different skill sets, become part of an acceleration test assessment meeting where the subject test item is evaluated against the acceleration test requirements and the type of test is identified. The team also identifies the intended operational and tie-down configuration, assesses the means in which components and subcomponents are mounted to the system, and all other concerns related to acceleration requirements. The overall process is depicted in Figure 1.

The initial task of the integrated team is to evaluate the test article for any inherent safety concerns. For example, the ATB team identified that AE devices weighing less than five pounds are usually

perceived to pose no substantial risks due to acceleration; therefore, a quick assessment and description of the equipment tie-down were found satisfactory. Generally, the team conducts a test selection meeting for the items weighing more than 5 pounds.

When the test team finds product-level tests are required, the article is tested in a physical environment, namely sled tracks or cen-

FIGURE 1. ACCELERATION TEST AND EVALUATION PROCESS
DIAGRAM



Note. CONOPS = Concept of Operations; SIM = Simulation.

trifuges, or a model representing the product can be developed and analyzed using FEA simulation. The component-level tests refer to the tests specific to a subcomponent or a structural member of the equipment, i.e., mounting brackets, screws, beams, straps, etc. When the decision is a component-level test type, the ATB team applies the ELT method by conducting an in-depth evaluation of the test article, identifying the critical areas within the item, and noting any potential safety concerns within the environment. The outcome of this evaluation is a list of tasks that includes a series of tests, analysis, inspections, and evaluations. The component-level test requires a final assessment meeting where the ATB team analyzes and deems acceptable the component-level test results or determines whether additional tasks are required.

Prior to 2008, acceleration tests were typically conducted at the product level. However, the case studies presented in this article highlight a multitude of alternative test options for component-level testing as well. When selecting between product or component-level testing, the ATB carefully considers many different aspects of the overall design of the equipment, its intended use, and any unique safety concerns. For example, component-level testing would most likely not be adequate for a system containing compressed gas cylinders because this form of testing would only target the key structural features of the system, such as the handles on the outer case. Rather, a product-level test, such as a sled test, would be more appropriate as it would test the whole system including the connections between the cylinders and the system where dangerous leaks could occur.

The component-level test was recently added to the acceleration test process and has saved a significant amount of time and money since 2008; therefore, the ATB places emphasis on the component-level test, unless the product must be tested in a physical environment. The component-level test uses the ELT method, which is detailed in the following section.

The ELT Method

The ELT terminology used in this article refers to the constant, or approximately constant, loading that is applied to the test item for a finite duration. The magnitude, point of application, and the direction of the load are equivalent to the properties of inertial loads and moments generated in an acceleration event under the g-levels shown in Table 1. The levels represented in this table are some of the common test requirements for AE equipment as outlined by the aircraft system organizations. The magnitudes shown in this table are consistent with Title 14 Federal Aviation Administration regulations, like Special Federal Aviation Regulation 23.787, which dictates that

the equipment tie-downs and restraints must sustain a 9g inertial load factor (Aeronautics & Space, 2010).

The magnitude of the equivalent load is determined using the magnitude of the sustained acceleration load that would be exerted on a tie-down component, a critical part, or a joint of the equipment in a physical test. For example, 9g of acceleration introduces 90 pounds inertial load on a device with 10 pounds of weight; and the critical areas, such as tie-downs and restraints, must be tested to verify they are capable of restraining the inertial loads and moments.

TABLE 1. TEST G-LEVELS USED FOR ACCELERATION TESTING

Forward (G)	Aft (G)	Up (G)	Down (G)	Lateral (G)
9	1.5	4	8	4

The authors reviewed the definition of static load and compared it to the definition of the sustained acceleration described in MIL-STD-810G Method 513.6 (Department of Defense, 2009). Shigley and Mitchell (1983) define a static load as “a stationary force or moment acting on a member” and identified the following attributes:

- Unchanging magnitude
- Unchanging point or points of application
- Unchanging direction

The following statements are also true for an acceleration test per the definition of acceleration found in MIL-STD-810G (Department of Defense, 2009):

- The magnitude of acceleration loading introduced to the EUT is sustained. In other words, a test is conducted for a certain period of time with a constant acceleration.
- Acceleration loading is applied to each axis independently; therefore, the point of application does not change during a test.
- Each direction of loading is applied independently; therefore, the direction of loading does not change.

Table 2 summarizes these definitions for identifying the attributes for a test load to use in the ELT method. This comparison helped determine the properties of the appropriate test loads used in ELT methodologies. For example, when a carrying handle is the key component used to restrain an EUT, the handle becomes the primary

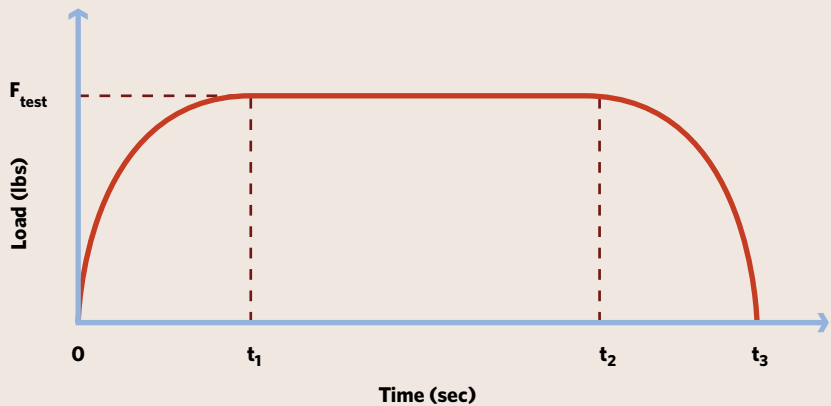
TABLE 2. ATTRIBUTES OF STATIC LOADING VS. EQUIVALENT
G-LOAD FOR TESTING PER MIL-STD-810G

Attribute	Static Loading	Acceleration G-Load in Testing (MIL-STD-810G, Method 513.6)	Test Load to use in the ELT Method
Load Magnitude	Constant	Sustained acceleration (Constant for a period of time)	Sustained loading for a period of time
Point or Points of Application	Unchanging	Tests are conducted at each direction independently	Unchanging
Direction	Unchanging	Tests are conducted at each direction independently	Unchanging

area of concern for the acceleration tests. As such, the handle may be tested using the ELT method. The test load would be sustained for a period of time, such as t_2 - t_1 as shown in Figure 2. The magnitude of the test load shown in Figure 2 (F_{test}), would be equivalent to the magnitude of the inertial forces generated by the acceleration g-levels, as illustrated in Table 1. The test load would be applied to a specific component or components previously identified as critical areas during the acceleration test assessment meeting.

The following sections describe both the acceleration test and evaluation process and ELT method using real case studies. The ATB decided to apply the test load for 6 seconds of duration after reviewing the military standards that describe the static tests. For example, MIL-STD-209K (Department of Defense, 2005) states the

FIGURE 2. CONCEPTUAL LOAD CURVE FOR EQUIVALENT LOAD



"loads applied in the vertical, longitudinal, and lateral directions shall be applied statically and independently for not less than 6.0 seconds." This duration became an ATB standard test parameter after gaining concurrence from the various aircraft system organizations. It was consistently used when the ELT method was selected for an acceleration test.

Case Studies

Table 3 shows some of the acceleration test and evaluation projects implemented since May 2008 using the new test process, as well as the ELT method described earlier. This section discusses some of the selected projects in the next subsections. As listed in Table 3, the ATB team applied the new process to a total of 14 projects and successfully used the ELT method in eight of those projects.

Case Study No. 1: ELT Approach for Testing a Lightweight Device (EUT No. 1)

EUT No. 1 is a lightweight medical device mounted in a small ruggedized case. The item weighs 6.23 pounds, and all components of the system are confined inside the case. In terms of acceleration testing, the only key feature of this equipment was its handle when secured to a patient litter as shown in Figure 3. The team decided to employ a tensile test on the handle and the handle mounting pins to evaluate the EUT under the previously stated acceleration criteria.

Figure 4 shows the ELT setup for a 9g acceleration test under the two worst-case loading scenarios assuming that the equipment may potentially slide out from between the strap and litter. Figure 5 shows the configuration of the EUT No. 1 on a tensile tester for two orientations. These are consistent with the identified test orientations shown

FIGURE 3. EUT NO. 1—TIE-DOWN ON A LITTER

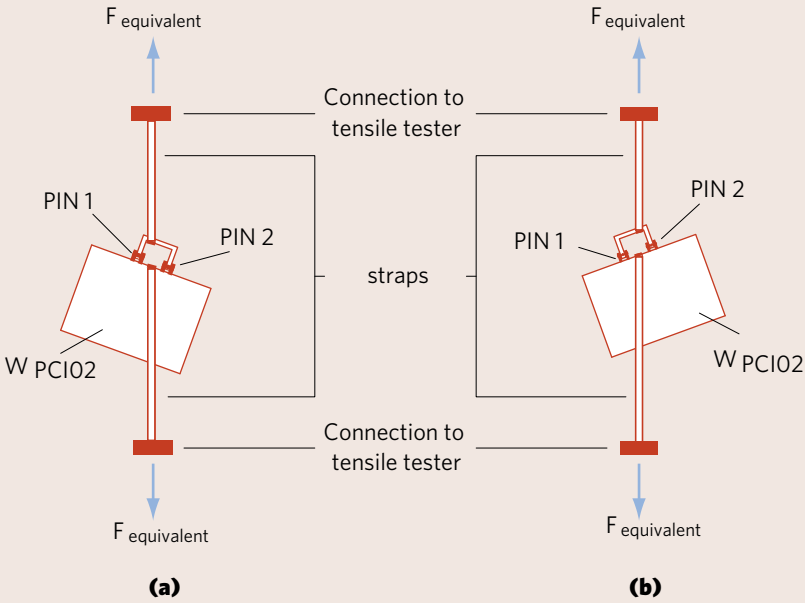




TABLE 3. EXAMPLE ATB ACCELERATION TEST AND EVALUATION PROJECTS

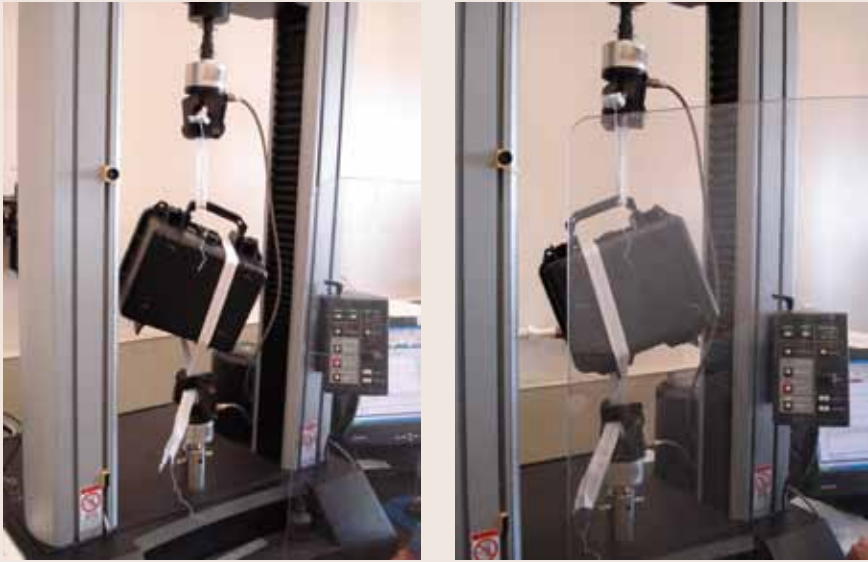
Project Number	AE Equipment Description	Case Study in this Article	Test Method
ATB-08-01	Lightweight device housed in a small, ruggedized container	EUT No. 1	ELT
ATB-08-02	Portable oxygen system in a protective cover	Not covered	ELT
ATB-08-03	Patient litter for accomodating patients up to 250 pounds	EUT No. 3	FEA (Product-Level Test)
ATB-08-04	Patient litter for accomodating oversize patients	EUT No. 3	FEA & ELT
ATB-08-05	Mechanical structure to attach AE devices to patient litters	EUT No. 3	FEA (Product-Level Test)
ATB-09-01	High-pressure oxygen system in a large, ruggedized container	EUT No. 4	Sled Testing
ATB-09-02	Electrical cables, plugs, and converters in a medium-sized, ruggedized container	Not covered	ELT
ATB-09-03	Patient monitor/defibrillator with about 16 pounds of weight	EUT No. 2	ELT
ATB-09-04	Neonatal transport system with heart and lung support	SUT No. 1	ELT
ATB-09-05	Smaller neonatal transport system structure	SUT No. 2	ELT
ATB-09-06	Mannequin with a control system	Not covered	ELT
ATB-09-07	Mannequin with a control computer	Not covered	ELT
ATB-09-08	Stacking litter structure	Not covered	ELT (in plan)
ATB-09-09	Small, portable electrical generation system in a carrying case	Not covered	Centrifuge Test (in plan)

FIGURE 4. EUT NO. 1—TEST CONFIGURATION ON A TENSILE TESTER

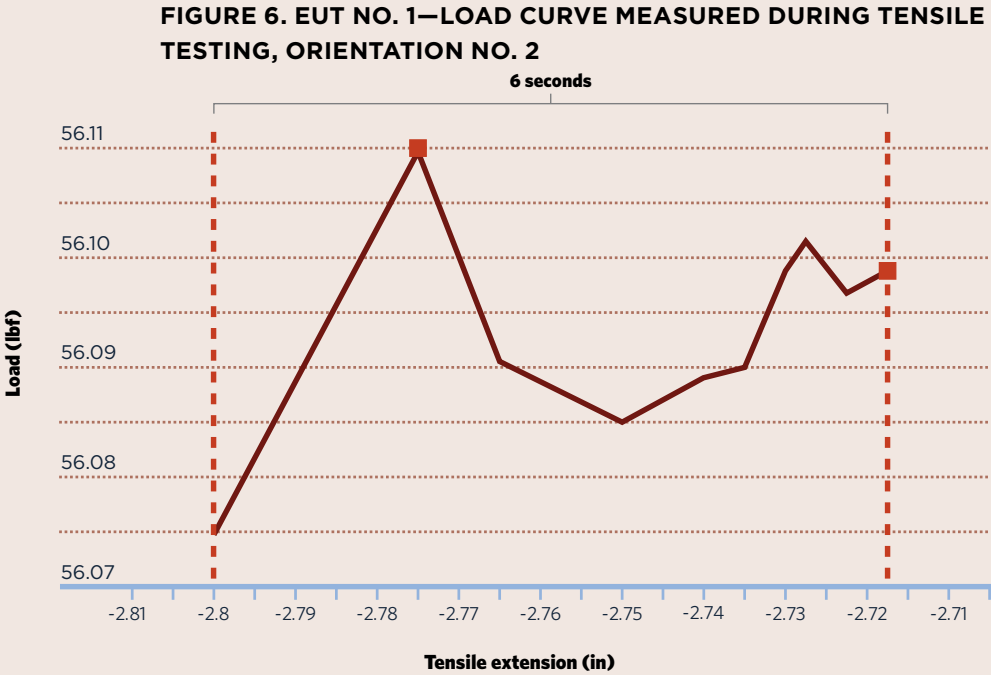


Note. (a) = Orientation 1; (b) = Orientation 2.

FIGURE 5. EUT NO. 1—ACTUAL TEST CONFIGURATIONS



Note. The image on the left coincides with Figure 4 (a), Orientation 1; the image on the right coincides with Figure 4 (b), Orientation 2.



in Figure 4. Figure 6 shows the actual record of the load applied for the Orientation No. 2. The test load was held at approximately 56 pounds-force for a 6-second duration.

When considering a physical test for EUT No. 1, the ATB estimated a substantially higher cost for the use of appropriate facilities, fixtures to hold the device during testing, and any expendable materials used during the test. In addition, a physical test would have required additional planning and coordination time, thus driving schedule delays and adding additional costs for manpower spent during planning. In this case, much of these cost and schedule risks were mitigated by using in-house tensile test stands.

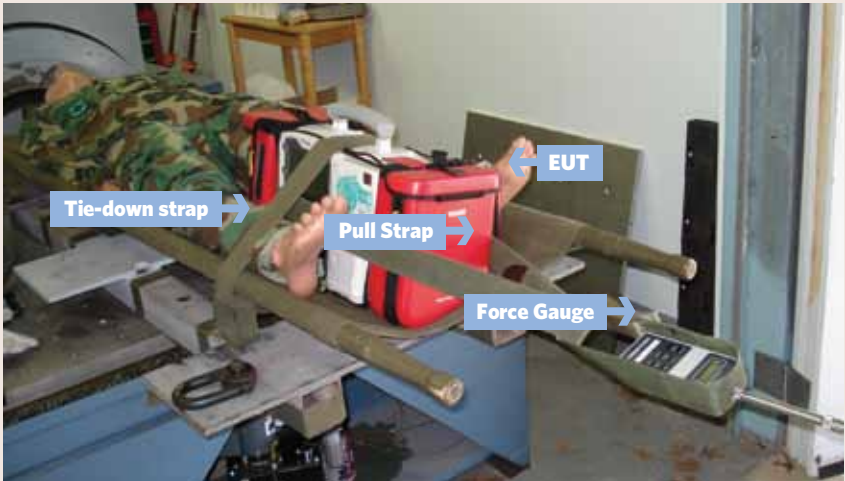
Case Study No. 2: ELT Approach Used in Testing of a Portable Monitor (EUT No. 2)

EUT No. 2 was a lightweight, portable, patient monitor/defibrillator weighing 16.2 pounds. The team’s main priority was to verify the item could be properly restrained such that it would not become a projectile during an acceleration event. To do so, the team came up with a tie-down method using litter straps to restrain the EUT’s movement in all directions. If successful, this tie-down method would become the approved method for restraining the device in the aircraft during operational missions. As shown in Figure 7, the litter strap passes through the handle of the EUT and the stirrup of the litter.

FIGURE 7. EUT NO. 2—TIE-DOWN ON A LITTER



FIGURE 8. EUT NO. 2—TEST SETUP



The team also noted that when the EUT is exposed to forward acceleration loads, it may potentially slide out from between the strap and litter. Under this scenario, the handle of the EUT would be required to bear the full 9g inertial load of the device. Therefore, the team conducted a pull test to verify this configuration restrains the EUT. This test would also verify the ultimate stresses of the handle were not exceeded if 146 pounds of equivalent load corresponding to 9g inertial load factor were applied through the EUT’s CG in the forward direction.

The team conducted a pull test in the configuration shown in Figure 8 using a calibrated force gauge for a 6-second duration. By using this in-house test method, the team was able to properly test the EUT under its operation configuration in less than 1 hour. Further, this test method only required the purchase of a new force gauge and accessories totaling \$1,250. If an FEA or sled tests were used on this

FIGURE 9. AE PATIENT TRANSPORT SYSTEM

device, estimated costs would start around \$30,000 and would take several weeks to plan and conduct the test.

Case Study No. 3: FEA Used in Testing of Patient Litters (EUT No. 3)

The team recently evaluated three AE articles used to move patients: two patient litters and a special structure used to attach medical devices onto the litter during transport. In this case, the team decided to perform an FEA using the ALGOR static stress and mechanical event simulator packages. The FEA results successfully identified components that may fail under the required acceleration loading on all three AE equipment items. Despite the successful use of FEA to identify potential safety risks, the time and money spent to evaluate these three devices were substantially higher than the methods discussed in the first two case studies. More than \$200,000 was spent on the FEA analyses over a one-and-a-half-year period. The decision to conduct an FEA on these three items was made prior to the development of the ELT method.

Case Study No. 4: ELT Approach Used for Test and Evaluation of a Complex Transport System Structure (System Under Test [SUT] No. 1)

The ATB team evaluated a structure of a complex system used to transport neonatal and pediatric patients in critical condition. The SUT, shown in Figure 9, contains 13 medical devices and weighs about 820 pounds. Due to the system's one-of-a-kind nature, as well as the cost and lead time associated with procuring the advanced medical devices mounted within it, the team consulted with several of the aircraft systems organizations and decided on using the ELT

TABLE 4. SAMPLE TASKS IDENTIFIED FOR THE ACCELERATION TEST AND EVALUATION OF SUT NO. 1

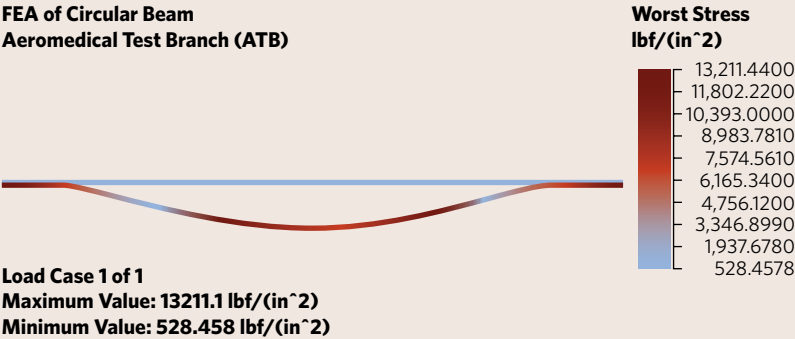
Task ID	Component	Task	Method
ATB-SUT1-001	D-rings	Perform a load test to verify that each tie-down ring is capable of holding 1 g of acceleration load.	Hang Test for D-rings; duration: 6 seconds Load analysis using the 12 cargo straps.
ATB- SUT1-002	Casters	Determine the load capacity of the casters. Identify the maximum payload. Determine the load and pressure distributions on the aircraft floor. Determine shoring requirements.	Manufacturing data CG calculation and analysis for finding the reaction loads and pressures. Finite Element Analysis (FEA) of the columns and top plate members.
ATB- SUT1-003	Locking Rod	Perform structural analysis on the locking rod and side bracket mounting screws used to secure the locking rod.	Finite Element Analysis
ATB- SUT1-004	Locking Rod	Verify proper alignment of the UPS units locking rod side brackets.	Instruction/Inspection
ATB- SUT1-005	Writing Table	Include requirement that the writing table is locked/stowed during takeoff, landing, and emergency situations.	Instruction/Limitation
ATB- SUT1-006	Padding	Ensure foam padding installed underneath the compressed gas cylinders.	Instruction/Inspection
ATB- SUT1-007	Straps	Verify the use of straps to restrain the handle of Medical Device No. 3 to the back housing bracket.	Analyze strap strength Instruction/Inspection
ATB- SUT1-008	Sliding Shelf Assemblies	Perform a pull test on all sliding shelf assemblies to demonstrate their ability to restrain the designated device under 4g lateral acceleration force.	Pull tests, 4g, each sliding shelf assembly; duration: 6 seconds

Note. CG = Center of Gravity; UPS = Uninterruptible Power Supply

FIGURE 10. VIEW OF SUT NO. 1 DURING HANG TEST



FIGURE 11. WORST STRESS FOR SUT NO. 1 LOCKING ROD



method. Employing this method, the team used a combination of analysis, inspection, and supporting tests to satisfy the acceleration test requirements. Therefore, this case study is covered in more detail than the previous case studies.

The acceleration test and evaluation team completed an in-depth structural analysis on the SUT during which 23 tasks were identified. These tasks included the test, inspection, and analysis of the structural members, restraint mechanisms, and tie-downs of SUT No. 1. For a description of the process, a sample of eight of the tasks is provided in Table 4.

The acceleration test team successfully conducted tests and performed analysis for each of the tasks identified in the assessment meeting. For example, the eight D-rings and four additional structural members were hang-tested, and the team subsequently verified that each tie-down location was capable of withstanding 1g acceleration load. Figure 10 shows a view of the SUT captured during one of the hang tests. When each tie-down location is used, the restraint capability for the system can sustain at least a 9g forward acceleration load.

Figure 11 shows the analysis results for the FEA of the locking rod, which demonstrated the locking mechanism is able to sustain 1.5g lateral loading. Additionally, the shoring was recommended based on the FEA results and in conjunction with sample calculations provided in MIL-STD-1791(2) (Department of Defense, 1997).

It is important to note that the ATB team previously considered using FEA for the acceleration testing of this SUT. However, projected cost and schedule figures similar to those noted in Case Study No. 3 discussed earlier negated the use of FEA on this system and required a new approach to meeting the acceleration requirement. In fact, initial estimates for the FEA started around \$474,000 and were scheduled to take an estimated 2 years to complete. The ATB is currently planning to apply the same approach for the test and evaluation of two similar transport structures, saving an estimated \$169,000 and 2 years of analysis time.

Case Study No. 5: Sled Testing of a High-Pressure Oxygen System in a Large, Ruggedized Container (EUT No. 4)

This EUT was a bulky, high-pressure mechanical system used to store large volumes of medical grade oxygen for patient use during transport. Weighing nearly 200 pounds, the system is housed in a ruggedized container and contains two large compressed gas cylinders. As mentioned earlier, applying an ELT test method would save substantial time and money; however, using this method would not adequately test the interaction of all components within the system.

More specifically, the ELT method would not test the reaction of the cylinders to the imposed acceleration load and how that reaction could affect the gauges, valves, and associated plumbing. Based on this rationale, the ATB team determined the accuracy and validity of the test data generated from a physical test far outweighed its cost and schedule risks, and the team began planning a sled test for the EUT. To further improve the relevance of the test and most accurately mirror its operational configuration, the team elected to test the EUT in its pressurized state, thus requiring the tests to be conducted at an outdoor facility.

The selection of this test method proved successful in assessing the safety of this EUT. Although the tests cost roughly \$30,000, required the construction of a containment structure and two special fixtures to hold the device, and took over 5 months to complete, the data generated from this sled test presented a very detailed prediction of how this EUT would perform during and after an acceleration event. This test also confirmed the intended tie-down configuration was capable of restraining the EUT during the g-loads shown in Table 1.

Conclusions

In the ever-changing world of acquisitions and the increasingly limited amount of money and time for testing activities, the ATB began exploring new test methods to satisfy acceleration testing requirements on AE equipment. The structured process described in this article continues to provide a methodical procedure for evaluating the safety of medical devices and determining the best method or combination of methods for conducting acceleration tests.

While this article discusses only certain aspects, much of this testing process is founded on a wealth of operational and technical experience. Additionally, each test article features unique characteristics that do not allow for standardization in the decision process. Because of these factors, the ATB team depends on the integrated team construct to help balance the decision process for each project.

Applying this process has already saved the ATB over \$900,000 in testing and analysis and cut more than 4 years from its busy test schedule. This process, including its dependence on an integrated team approach, has the ATB poised to continue to meet the demands of the constantly evolving acquisition environment in which today's acquisition practitioners must execute their programs.

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